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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,344	04/04/2008	Lawrence Solomon	SLP-036	2815

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EXAMINER	
LOVE, TREVOR M	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
09/14/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,344	SOLOMON ET AL.	
	Examiner	Art Unit	
	TREVOR M. LOVE	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8 and 10-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8 and 10-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made to Applicant's response filed 09/01/2010.

Claims 1-7 and 9 are cancelled.

Claims 8 and 10-13 are pending

No claims are currently amended.

Claims 8 and 10-13 are currently under consideration.

Maintained Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lieberman (1990, Pharmaceutical Dosage Forms - tablets) in view of Ullman et al (U.S. Patent number 4,215,104, Patent issued Jul. 29, 1980) and Geller (U.S. Patent number 3,927,194, Patent issued Dec. 16, 1975). This rejection is maintained.

Lieberman teaches a pharmaceutical dosage form with layers. Lieberman teaches that it is known to have a tablet wherein the center layer is free of active. Lieberman teaches said middle inert layer for when the two outer actives are incompatible (see first paragraph under “IV. Layer Tablets”). Lieberman further teaches that it is known to place scores on tablets to allow for manual breakage, however, Lieberman acknowledges that traditional scores result in significant variation in drug dose (see point number 4 under "Properties of Tablets"). Lieberman further teaches that the purpose of a score is "to permit breaking the tablet into equal parts for the administration of half a tablet" (see point number 4 under "Properties of Tablets").

Lieberman fails to directly teach that there are only two layers to the tablet, the particular location of the score, or the instant active ingredient.

Ullman teaches a multi-fractionable unitary tablet structure. The tablet has a score which transverses the entire tablet.

Geller teaches deeply scored tablets (up to 66% of the entire tablet) wherein the active ingredient is isosorbide dinitrate (see column 2, lines 28-33 and claim 6). Geller further identifies the art recognized deficiency in scored tablets i.e. "scores do not always assure precise division of the tablet" (see column 1, lines 40-41).

It would have been obvious to one or ordinary skill in the art at the time the invention was made to utilize the tablet structure of Ullman with the layers described in Lieberman. One would have been motivated to do so since Ullman provides a clear teaching of a superior scored tablet which allows for the tablet to be broken into two separate dosages. There would be a reasonable expectation of success since both Lieberman and Ullman are teaching scored tablets.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the top and bottom portion of the tablet design of Ullman for the incompatible active ingredients of Lieberman. One would have been motivated to do so since Lieberman teaches that variable dosing is a well known problem in the art associated with breaking dosage forms. Furthermore, utilizing the top and bottom segment of Ullman allows for breakage to only occur in the inert barrier layer. There would be a reasonable expectation of success since Lieberman teaches that trilayered tablets with an inert barrier layer can be scored.

It further would have been obvious to one of ordinary skill in the art at the time the invention was made, given the scored trilayered tablet of Lieberman and Ullman

which comprises two incompatible drugs separated by a barrier layer, to remove one of the drug layers of the composition of Lieberman and Ullman, should one desire to only deliver one of the actives, such as is taught in Geller, namely a scored tablet with only one active. One would have been motivated to retain the inert barrier layer since said barrier layer has allowed for the overcoming of the well known problem in the art of variable dosages. There would be a reasonable expectation of success since the removal of one of the actives would not affect the dosage of Lieberman and Ullman. It is further noted that removal of one of the actives is clearly obvious if one only desires to deliver one active, see MPEP 2144.04, which states: “Omission of an element and its function is obvious if the function of the element is not desired (see *Ex parte Wu* , 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989)).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize drugs directed toward the treatment of cardiovascular conditions in the tablet of Lieberman in view of Ullman. One would have been motivated to do so since Geller teaches that it is useful to be able to provide divided doses of isosorbide dinitrate. There would be a reasonable expectation of success in the use of isosorbide dinitrate since as is seen by Geller, isosorbide dinitrate is known to be advantageously administered by tablets which can be broken into smaller dosing units.

With regard to the distance of said score, it is noted that the instant claims are directed to the score being "at least” or “no less than” 70% of the distance from the top of the first layer to the interface (namely, the first layer), wherein it is noted that the

teachings of Geller are that the score is 66% of the entire tablet. Therefore, the score of Geller which is 66% through the entirety of the tablet reads on the limitation of 70% or more through only the first layer.

Response to Arguments

Applicant argues in the remarks filed 09/01/2010 that there is no nexus in Lieberman for a three layer tablet and scoring the tablet for breaking, and Applicant states that "[t]he Examiner did not acknowledge that the portion of Lieberman that was relied upon for the teaching of the three-layer tablet was on page 274 while page 172 of Lieberman was also the section cited for its teaching that the purpose of a score was to permit breaking the tablet into equal parts for administration of a half a tablet" (see Remarks, page 4). Applicant's argument is not found persuasive, it is noted that the Final Office Action mailed 03/22/2010 wherein the Examiner stated "Applicant's arguments are not found persuasive since, as is clearly seen by page 274 of Lieberman, the section discussing layered tablets directly states that "markings may be impressed in the surfaces of the multilayered tablet", wherein the best place to look for what said markings can be within the same reference. Hence, when Lieberman teaches on page 132 that "[a]nother marking that may appear on the tablet is a score", it is clear that Lieberman is teaching that multilayered tablets can be scored" (see Final Office Action, mailed 03/22/2010, page 8). There is therefore a clear nexus, which was clearly identified in the previous Office Action. Therefore, Applicant's arguments are again found unpersuasive. Applicant argues that one of ordinary skill in the art, having the desire to create a two layer tablet would not approach said problem by elimination of

a layer from a three layered tablet. Applicant's argument is not found persuasive since the three layered tablet of Lieberman as modified by Ullman and Geller would have an advantageous property in the three layered form, which would also extend to the two layered form. Further, Applicant is reminded that "A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton." KSR, 550 U.S. at __, 82 USPQ2d at 1397. "[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." Id. Office personnel may also take into account "the inferences and creative steps that a person of ordinary skill in the art would employ." Id. at _ , 82 USPQ2d at 1396. Applicant further argues that the citation of *In re Larson* and *In re Kuhle* in the previous action were improper since said cases were directed to elimination of a structural component, wherein one of ordinary skill would have further eliminated the middle layer should the modification identified by the Examiner been preformed. Applicant's argument is not found persuasive since one of ordinary skill would have appreciated the advantage associated with said layer in the tri-layered tablet and that said feature would perform the same function in a bi-layer tablet. Finally, Applicant argues that there is no reason to modify the composition of Lieberman with the score of Geller. Applicant's argument is not found persuasive since Lieberman clearly identifies the disadvantage associated with dosage variation, wherein Geller identifies a method of minimizing said disadvantage. Therefore, Applicant's arguments are not found persuasive.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 8 and 10-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 53 of copending Application No. 10/598,355.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and '355 are directed to a bilayered tablet wherein the first layer comprises active and the second layer is substantially free of drugs. Both compositions are score, and are designed to be broken and administered.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant states that a terminal disclaimer will be filed upon indication of allowable subject matter. Applicant's argument has been considered, however, since the claims are not in condition for allowance, and a terminal disclaimer has not been filed, the rejection is maintained.

Conclusion

No claims allowed. All claims rejected. No claims objected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TREVOR M. LOVE whose telephone number is (571)270-5259. The examiner can normally be reached on Monday-Thursday 7:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TL

/David J Blanchard/
Primary Examiner, Art Unit 1643